UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,353	07/10/2003	Kenneth J. Vosniak	60497.000014	1558
<sup>21967</sup> HUNTON & W	7590 03/16/201 YILLIAMS LLP	EXAMINER		
INTELLECTUAL PROPERTY DEPARTMENT			WEATHERBY, ELLSWORTH	
1900 K STREET, N.W. SUITE 1200		ART UNIT	PAPER NUMBER	
WASHINGTON, DC 20006-1109			3768	
			MAIL DATE	DELIVERY MODE
			03/16/2010	PAPER

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/616,353	VOSNIAK ET AL.				
Office Action Summary	Examiner	Art Unit				
	ELLSWORTH WEATHERBY	3768				
The MAILING DATE of this communication app	pears on the cover sheet with the c	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING Do  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period v  - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>11/0</u> 3	3/2009					
• • • • • • • • • • • • • • • • • • • •	action is non-final.					
· <u> </u>						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	parto qualyto, 1000 0.21 11, 10					
· <u> </u>						
4) Claim(s) <u>1-6,8-17 and 19-37</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) <u>1-6,8-17 and 19-37</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	r election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	r.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Ex	caminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) ☐ Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	)-(d) or (f).				
a)  All b) Some * c)  None of:						
1.☐ Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
	·					
Attachment/s)						
Attachment(s)  1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate				
3) Information Disclosure Statement(s) (PTO/SB/08)	5) Notice of Informal P	atent Application				
Paper No(s)/Mail Date	6)					

#### **DETAILED ACTION**

## Claim Objections

1. Claims 5-6, 8, 16-17, 26-28, and 30 are objected to because of the following informalities: Regarding claims 5, 16 and 26, exemplary claim language including, "wherein the data entry step *comprises: downloading information from a central database; and entering data locally at a sight where the scan takes place*", is unclear. Here, the claim language does not make clear whether or not the data entry step inclusively or exclusively comprises the downloading information from a database step and the entering data locally step. Regarding claims 8 and 30, it is not made clear by the claim language whether or not the memory which stores the computer program is related to the programmed processor. For the purpose of examination the Examiner is interpreting the programmed processor as executing the computer program stored on the memory. Appropriate correction is required.

#### Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 3. Claims 1-6, 25-29 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use

the invention. Regarding claims 1-37, the Specification fails to set forth the means by which tomography images would be obtained. That is, in the field of tomography it is known that a scanogram or a scout scan must initially be acquired to establish a frame of reference for a subsequent tomographic image. Each time a patient is placed on the tomographic scanner bed there intrinsically exists uncertainty comprising the positioning of the location of the target anatomy relative to the location of the orthogonal scan plane. A standard procedure in CT, MRI and PET imaging, initially acquires a scoutscan or scanogram to provide a frame-of-reference by localizing the position of a reference anatomy relative to the transverse image plane. This position information is required to subsequently window the image acquisition on the target anatomy. Therefore, it is not clear by the claims or the specification how the data entry step relating to a scan is completed before the scan begins when the specification is silent with regard to localizing the patient anatomy in tomography.

### Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 2 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 2, the claim limitation, "entering all data necessary for the imaging device to begin the second scan" is undefined. First, there appears to be two data entry steps, a first data entry step & a second data entry

Art Unit: 3768

step. Thus, it is not clear which data entry step to which claim 2 is referring.

Furthermore, the claim language all data necessary is not defined. That is, in order to determine the scope of "all data necessary" the Examiner would need to guess the extent of *all* necessary data. For the purposes of examination, the Examiner is interpreting all data necessary to comprise: a requested scan, a patient name or a patient ID, or a protocol, or an indication that a patient is ready for a scan protocol. Regarding claim 30, the claimed "programmed to allow an operator to specify..." is unclear. Here, the scope of allowing an operator to perform a function is unclear.

## Claim Rejections - 35 USC § 101

#### 6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim language, "at least one memory which stores at least one computer program" includes subject matter that is not directed to one of the four patent-eligible subject matter categories. That is, memory which stores at least one computer program may include transitory signals having a computer program for executing the steps, which are non-statutory. The claim should read at least one non-transitory memory having a computer program stored thereon which configures the processor...

#### Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 8. Claims 19, 23-24, 30-31, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Banks et al. (USPN 6,674,449).
- 9. Banks teaches a method for configuring an imaging device (Abstract; Figs. 1-10), comprising: specifying at least one criterion for determining a next patient to be scanned (refs. 234, 236, 238, 240, 242) and storing the criterion in a preferences database (col. 10, II. 10-65); and applying the at least one criterion (e.g. scheduled time) to a plurality of scheduled patients and receiving an identification of the next patient to be scanned based on the at least one criterion (col. 11, II. 26-55; ref. 230). Here, a patient schedule icon 222 brings up image 232 having patient and scan specific information for the next patient to be scanned (col. 12, II. 5-45); and configuring the scanner for the next patient to be scanned (col. 12, I. 36- col. 13, I. 25). Banks also teaches a detector for detecting magnetic radiation during a data acquisition of a scan (ref. 152).

## Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 11. Claims 1-5, 8-16, 25-26, 28-29 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Damadian et al. (USPN 5,623,927) in view of Banks et al. (USPN 6,674,449).
- 12. Damadian et al. (hereinafter Damadian) teaches a system and method for improving patient throughput in an MR imaging device where patient handling time and scan protocol time are reduced in a multipatient imaging system (Abstract; Figs. 1-10). By providing a system that multiplexes the patient handling and the necessary scan protocol steps, the patient handling of one patient is overlapped with the scanning of a second patient (abstract; col. 2, II. 42-50). Here, Damadian teaches performing patient handling for one patient while the scanning is being conducted on a different patient (col. 2, II. 42-50). That is, Damadian anticipates completing a first data entry step necessary to begin a data acquisition step for a first scan and simultaneous with the data acquisition step of the first scan a second patient is prepared for the scanning in a subsequent magnetic resonance imaging procedure (col. 2, II. 18-36; col. 4, II. 46-55). Damadian even teaches that during the scanning of a first patient a second patient is prepared to undergo a second scan protocol, which when complete the patient is ready

to undergo the scan protocol (col. 7, II. 5-45: e.g. all data necessary for the imaging device to begin the second scan). Furthermore, it is disclosed that this parallel preparation and scanning is controlled by digitally programmable electronics which are part of the standard magnetic resonance imaging apparatus (Here, the Examiner is interpreting the claim 8 limitations, "a memory", "computer program" and a "processor" to be met).

- 13. Damadian teaches all the limitations of the claimed invention except for expressly teaching that the patient handling comprises entering scan configuration data related to the second scan into the scan processing unit. Damadian also does not expressly teach that the step of beginning the data acquisition step for the second scan comprises commanding the imaging device to determine a next patient to be scanned and verifying the identity of the patient arriving at the scanner. Damadian also does not expressly teach that the data entry step comprises: downloading information from a central database; and entering data locally at a sight where the scan takes place. Damadian does not expressly teach that the system comprises a PET, CT or an X-ray scanner. Damadian also does not expressly teach specifying criterion for determining a next patient to be scanned and storing the criterion in a preference database to determine the next patient to be scanned based on the criterion.
- 14. In a related field of endeavor, Banks et al. (hereinafter Banks) teaches an optimized means for managing multiple imaging processes in a medical imaging environment (abstract). Banks goes on, teaching that the patient handling is typically done in accordance with a prescribed scan type or scan protocol (col. 3, II. 2-25; Fig. 2).

The system disclosed by Banks includes completing data entry steps including entering scan configuration data [e.g. 200, 236, 240, 238] related to a first scan into a scan processing unit [e.g. 100,106, 122] (col. 9, II. 7-45; col. 10, II. 29-65; col. 12, I. 65- col. 13, I. 15: Here, a patient schedule icon 222 brings up a image 232); beginning a data acquisition step for the first scan (col. 11, II. 46-55); completing the first scan and beginning a data acquisition step for a second subsequent scan (col. 16, II. 25-28). Banks also teaches performing imaging according to a central patient schedule (See Fig. 3). Therein, a patient identification is verified locally by a tech to complete the imaging request form and to enter necessary data relating to a scan protocol (col. 12, II. 25-64; Figs. 4-5). Banks also teaches controlling any of a plurality imaging modalities, e.g. CT, NM (col. 1, II. 15-48; col. 5, II. 54-65). Banks also teaches specifying at least one criterion for determining a next patient to be scanned (refs. 234, 236, 238, 240, 242) and storing the criterion in a preferences database (col. 10, II. 10-65); and applying the at least one criterion (e.g. scheduled time) to a plurality of scheduled patients and receiving an identification of the next patient to be scanned based on the at least one criterion (col. 11, II. 26-55; ref. 230). Here, a patient schedule icon 222 brings up image 232 having patient and scan specific information for the next patient to be scanned (col. 12, II. 5-45); and configuring the scanner for the next patient to be scanned (col. 12, I. 36- col. 13, l. 25). Banks also teaches a detector for detecting magnetic radiation during a data acquisition of a scan (ref. 152).

15. Because both Damadian and Banks are in the field of optimizing imaging workflow, it would have been obvious to modify the controlling electronics for

simultaneous patient preparation and scanning of Damadian in view of the means for managing imaging workflow according to a patient schedule and required scan configuration of Banks. The motivation to modify Damadian in view of Banks would have been to improve patient throughput by incorporating known HIS or CIS means, as disclosed by Banks.

- 16. Claims 6, 17 and 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Damadian et al. (USPN 5,623,927) in view of Banks et al. (USPN 6,674,449) as applied to claims 5, 16, 26 above, and further in view of Waku et al. (Pub. No.: 2002/0099571).
- 17. The imaging system of Damadian in view of Banks teaches all the limitations of the claimed invention except for expressly teaching that the step of entering data locally comprises entering radioactive tracer information.
- 18. In a related field of endeavor, Waku et al. (hereinafter Waku) teaches a method of configuring a scan in an imaging device comprising data acquisition for a first patient (fig. 4) wherein basic patient information is input [0036; 0172; 0136-0147]. Information may be downloaded from a central or global database (fig. 16) and also may be entered locally. Parameters for a scan are entered, such as the contrast medium desired [0141] and the plans for the scan, or scan protocol [0142].
- 19. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the imaging system of Damadian in view of Banks with the locally inputted patient information of Waku. The motivation to modify Damadian in view of

Banks with Waku would have been to provide any relevant imaging information, including the radioactive tracer information, as disclosed by Waku.

- 20. Claims 20-22 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banks et al. (USPN 6,674,449) in view of Waku et al. (Pub. No.: 2002/0099571).
- 21. The imaging system of Banks teaches all the limitations of the claimed invention except for expressly teaching that the step of entering data locally comprises entering radioactive tracer information, arrival time or registration time.
- 22. In a related field of endeavor, Waku et al. (hereinafter Waku) teaches a method of configuring a scan in an imaging device comprising data acquisition for a first patient (fig. 4) wherein basic patient information is input [0036; 0172; 0136-0147]. Information may be downloaded from a central or global database (fig. 16) and also may be entered locally. Parameters for a scan are entered, such as the contrast medium desired [0141] and the plans for the scan, or scan protocol [0142]. Here, the Examiner stands that patient arrival time or patient registration time are obvious variants of the scheduled time or status of Banks and the examination order of Waku because each disclose the ordering of patients based on time and availability data.
- 23. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the imaging system of Banks in view of the locally inputted patient information of Waku. The motivation to modify Banks with Waku would have been to

Art Unit: 3768

provide any relevant imaging information, including the radioactive tracer information, as disclosed by Waku.

#### Response to Arguments

24. Applicant's arguments, filed 11/03/2009, with respect to the rejection(s) of claim(s) 1-3, 8-14 and 36-37 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/ Supervisory Patent Examiner, Art Unit 3768